

**IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF TENNESSEE  
WESTERN DIVISION AT MEMPHIS**

AVANOS MEDICAL SALES, LLC.

Plaintiff,

v.

MEDTRONIC SOFAMOR DANEK USA,  
INC., MEDTRONIC, INC., AND  
MEDTRONIC PLC,

Defendants.

Civil Action No. \_\_\_\_\_

**JURY DEMANDED**

**COMPLAINT**

Plaintiff Avanos Medical Sales, LLC (“Avanos” or “Plaintiff”), for their Complaint against Medtronic Sofamor Danek, USA, Inc., Medtronic, Inc., and Medtronic PLC (collectively, “Medtronic” or “Defendants”), to the best of their knowledge, information, and belief, hereby assert as follows:

**NATURE OF THE ACTION**

1. This is a civil action for infringement of United States Patent No. 8,882,755 (the “755 patent”), arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

**THE PARTIES**

2. Plaintiff Avanos Medical Sales, LLC, is a company organized and existing under the laws of the state of North Carolina, with its principal place of business at 5405 Windward Parkway, Alpharetta, GA 30004.

3. Upon information and belief, Defendant Medtronic Sofamor Danek USA, Inc., is a company organized and existing under the laws of the state of Tennessee with its principal office at 2600 Sofamor Danek Drive, Memphis, TN 38132.

4. Upon information and belief, Defendant Medtronic, Inc., is a company organized and existing under the laws of the state of Minnesota. Upon information and belief, Medtronic, Inc., has a regular and established place of business at 4340 Swinnea Road, Shelby, Memphis, TN 38118.

5. Upon information and belief, Defendant Medtronic PLC is an Ireland corporation with its principal executive office at 20 Lower Hatch Street, Dublin 2, Ireland. Upon information and belief, Medtronic PLC has a regular and established place of business at 2600 Sofamor Danek Drive, Memphis, TN 38132.

### **INTRODUCTION**

6. Avanos is a pioneering medical-device company that specializes in the treatment of neuropathic pain. Avanos and its predecessors have devoted significant time and money developing products to treat chronic pain using radiofrequency ablation (“RFA”). Avanos manufactures and sells COOLIEF\*® (“Coolief”), a groundbreaking RFA system that incorporates water-cooling technology and improvements in temperature monitoring to more effectively and safely deactivate difficult-to-reach nerves that transmit pain signals to the brain. Coolief offers patients a non-narcotic, minimally invasive, and effective pain management solution. For the last ten years, Avanos has led the market in offering water-cooled RFA pain relief.

7. RFA treats pain by selectively targeting nerves and impeding their ability to transmit pain signals to the brain. Once treated by an RFA procedure, those nerves will not conduct pain signals until the nerve cells regenerate.

8. In an RFA procedure, a physician applies one or more needle-like probes to the site of the targeted nervous tissue. These probes have electrically conductive electrodes at their tip that emit radiofrequency (RF) energy to the targeted tissue. The RF energy agitates the electrons in the nerve cells adjacent to the probe tip. This agitation generates friction, which heats up the tissue and breaks down the cells' proteins, resulting in the formation of a lesion in the nervous tissue. In effect, the RF energy delivered through the probes "ablates" the nerves, resulting in long-term pain relief.

9. Cooled-RF ablation refers to RFA procedures where the ablating probe is internally cooled with circulating fluid. Cooled-RF ablation is an improvement over non-cooled RFA because the circulating fluid cools the surrounding tissue, which allows more RF energy to be safely delivered to target nerves and creates lesions that are larger in volume.

10. Conventional and cooled RF procedures are increasingly popular alternatives to traditional methods of managing chronic pain. Avanos's Coolief RFA therapy safely and effectively treats chronic back, knee, and hip pain, and the pain relief can last for up to one year. The therapy helps improve patients' quality of life with a reduced need for opioids or other narcotic treatments. Cooled RF treatments also provide greater, longer-lasting pain relief for osteoarthritis knee pain than steroids through an outpatient procedure that is minimally invasive relative to surgical treatments.

11. The '755 patent claims a technological improvement over prior RFA systems. Among other things, the claimed inventions allow physicians to create larger lesions with accurate temperature monitoring of the target tissue, maintaining the benefits of cooled-RF ablation while delivering RF energy in a safe, controlled, and predictable manner.

12. On or about February 27, 2019, Medtronic announced United States Food and Drug Administration (“FDA”) 510(k) clearance of the Accurian system. The Accurian system includes, among other things, a radiofrequency generator and probes that can be used with the generators. Upon information and belief, Medtronic makes, uses, sells, offers for sale, and imports “enhanced” components for the Accurian system. The “enhanced” components are for use in cooled-RF procedures. Upon information and belief, these components include the RF generator and stand, a pump with stand, an enhanced hub, and single-use internally cooled probes.

13. The Accurian RFA system is indicated for the creation of radiofrequency lesions in nervous tissue. Upon information and belief, physicians use, and will use, the enhanced Accurian RFA system to treat pain by creating radiofrequency lesions in nervous tissue in the body.

14. By making, using, selling, offering for sale, and importing the Accurian system products, including internally cooled-RF products, Medtronic infringes the claims of Avanos’s ’755 patent.

15. Upon information and belief, Medtronic’s infringement of the ’755 patent has been knowing and willful.

16. For example, Medtronic’s 510(k) premarket notification of intent to market the Accurian system relies on previously FDA-approved Avanos Coolief products as “Predicate Devices” to demonstrate the Accurian’s safety and efficacy. Medtronic certified to the FDA that “performance testing was completed to demonstrate substantial equivalence” of the Accurian system to Coolief products.

17. Upon information and belief, Medtronic engaged Josh White, Avanos’s former Director of Sales for Interventional Pain Management, to assist in the marketing and promotion of the Accurian system.

18. The contract manufacturer of Medtronic's Accurian system is the same company that partnered with Avanos's predecessor to develop Avanos's Coolief products.

19. Avanos's '755 patent has been cited several times by Medtronic and/or Medtronic-related entities in the prosecution of patents related to radiofrequency ablation, including:

- U.S. Patent No. 7,987,001;
- U.S. Patent No. 8,374,673;
- U.S. Patent No. 9,510,905;
- U.S. Patent No. 9,517,103;
- U.S. Patent No. 9,636,164;
- U.S. Patent No. 9,993,178;
- U.S. Patent No. 9,993,283;
- U.S. Patent No. 9,993,283; and
- U.S. Patent No. 10,166,062.

### **JURISDICTION**

20. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

21. This Court has personal jurisdiction over Medtronic Sofamor Danek USA, Inc., Medtronic, Inc., and Medtronic PLC because, *inter alia*, Medtronic Sofamor Danek USA, Inc., Medtronic, Inc., and Medtronic PLC have committed tortious acts of patent infringement under 35 U.S.C. §271(a)–(c) and intend a future course of conduct that includes acts of patent infringement in the Western District of Tennessee. Upon information and belief, Medtronic Sofamor Danek USA, Inc., Medtronic, Inc., and Medtronic PLC have made, used, sold, have offered to sell, and

imported, and continue to make, use, sell, offer for sale, and import the Accurian radiofrequency generator and enhanced probes (the “Accused Products”) in this state and judicial district.

22. Upon information and belief, Medtronic Sofamor Danek USA, Inc., Medtronic, Inc., and Medtronic PLC have substantial, continuous, and systematic contacts with the Western District of Tennessee.

23. Upon information and belief, Medtronic Sofamor Danek USA, Inc., Medtronic, Inc., and Medtronic PLC have distribution channels throughout the United States, including in this state and judicial district. By advertising the Accused Products on the Medtronic website, without restricting that advertisement to a particular geographic area, Defendants have made clear that they intend to use Medtronic’s national distribution channels to distribute and sell the Accused Products throughout the United States, including the Western District of Tennessee, which would have a substantial effect on the Western District of Tennessee. Medtronic Sofamor Danek USA, Inc., Medtronic, Inc., and Medtronic PLC have introduced products that practice the claims of the ’755 patent into the stream of commerce with the knowledge, or reasonable expectation, that actual or potential users of such products are located within the Western District of Tennessee.

24. Upon information and belief, Defendants are in the business of, among other things, manufacturing and selling medical devices and medical products. Upon information and belief, Defendants, themselves and through their subsidiaries, affiliates, and agents, manufacture, import, market, distribute, and/or sell medical devices and medical products, including the Accused Products, throughout the United States and this District.

25. Upon information and belief, Defendants hold themselves out as a single entity, are agents of each other, and/or work in concert with each other with respect to the manufacture,

regulatory approval, marketing, sale, importation, and distribution of the Accused Products throughout the Western District of Tennessee and the United States.

26. Upon information and belief, Medtronic Sofamor Danek USA, Inc., has previously submitted to the jurisdiction of this Court. *See Spine Solutions, Inc. v. Medtronic Sofamor Danek, Inc.*, Ca. No. 2:07-cv-02175-JPM.

27. This Court has personal jurisdiction over Medtronic Sofamor Danek USA, Inc., by virtue of, among other things, (1) its continuous and systematic contacts with the United States, including the Western District of Tennessee, (2) its incorporation and business registration in the state of Tennessee, (3) its acts of tortious patent infringement in the Western District of Tennessee, (4) its sale of a substantial volume of medical devices and products in the Western District of Tennessee, (5) its maintenance of its principal place of business at 2600 Sofamor Danek Drive, Memphis, TN 38132, and (6) its conduct by, through, and in concert with Medtronic, Inc., and Medtronic PLC.

28. Upon information and belief, Medtronic, Inc., has previously submitted to the jurisdiction of this Court. *See Thompson et. al. v. Medtronic, Inc.*, Ca. No. 2:19-cv-02038-JPM.

29. Upon information and belief, Medtronic, Inc., is registered to do business in the state of Tennessee, and has a registered agent for service of process at Corporation Service Company, 2908 Poston Avenue, Nashville, TN 37203-1312.

30. Upon information and belief, this Court has personal jurisdiction over Medtronic, Inc., by virtue of, among other things, (1) its continuous and systematic contacts with the United States, including the Western District of Tennessee, (2) its business registration in the state of Tennessee, (3) its acts of tortious patent infringement in the Western District of Tennessee, (4) its sale of a substantial volume of medical devices and products in the Western District of Tennessee,

(5) its maintenance of a regular and established place of business in the Western District of Tennessee at 4340 Swinnea Road, Shelby, Memphis, TN 38118, and (6) its conduct by, through, and in concert with Medtronic Sofamor Danek USA, Inc., and Medtronic PLC.

31. Upon information and belief, Medtronic PLC has previously submitted to the jurisdiction of this Court. *See Thompson et. al. v. Medtronic, Inc.*, Ca. No. 2:19-cv-02038-JPM.

32. Upon information and belief, this Court has personal jurisdiction over Medtronic PLC by virtue of, among other things, (1) its continuous and systematic contacts with the United States, including the Western District of Tennessee, (2) its acts of tortious patent infringement in the Western District of Tennessee, (3) its sale of a substantial volume of medical devices and products in the Western District of Tennessee, (4) its maintenance of a regular and established place of business in 2600 Sofamor Danek Drive, Memphis, TN 38132, and (5) its conduct by, through, in concert, and in privity with Medtronic, Inc., and Medtronic Sofamor Danek USA, Inc.

33. In the alternative, this Court has personal jurisdiction over Medtronic PLC under Federal Rule of Civil Procedure 4(k)(2)(A).

### **VENUE**

34. The preceding paragraphs are incorporated by reference as if set forth fully herein.

35. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400.

36. Venue is proper in this jurisdiction over Medtronic Sofamor Danek USA, Inc., pursuant to 28 U.S.C. § 1400 because Medtronic Sofamor Danek USA, Inc., is incorporated in Tennessee. Venue is further proper because Medtronic Sofamor Danek USA, Inc. maintains a regular and established place of business in Tennessee, and has committed acts of infringement in this District.



37. Venue is proper in this jurisdiction over Medtronic, Inc., pursuant to 28 U.S.C. § 1400 because Medtronic, Inc., maintains a regular and established place of business in Tennessee, and has committed acts of infringement in this District.

38. Venue is proper in this jurisdiction over Medtronic PLC pursuant to 28 U.S.C. § 1391. Upon information and belief, Medtronic PLC is an Ireland corporation, and therefore may be sued in any judicial district where it is subject to the Court's personal jurisdiction.

39. In the alternative, venue is proper in this jurisdiction pursuant to 28 U.S.C. § 1400 over Medtronic PLC because Medtronic PLC maintains a regular and established place of business in Tennessee and has committed acts of infringement in this District.

#### **THE PATENT-IN-SUIT**

40. The '755 patent, entitled "Electrosurgical Device for Treatment of Tissue," was duly and legally issued by the United States Patent and Trademark Office on Nov. 11, 2014. A copy of the '755 patent is attached hereto as **Exhibit A**.

41. The '755 patent relates to a cooled "novel medical probe assembly, system, and methods for the use thereof to treat tissue[.]" (Ex. A, '755 Patent at Abstract.) Specifically, the patent explains "the probe assemblies and system described herein are particularly useful to deliver radio frequency energy to a patient's body. RF energy delivery may be used for various applications, including the treatment of pain[.]" (*Id.*)

42. As the specification of the '755 patent explains, "in order to extend the size of a lesion, radio frequency treatment may be applied in conjunction with a cooling mechanism, whereby a cooling means is used to reduce the temperature of the tissue in the vicinity of an energy delivery device, allowing a higher voltage to be applied without causing an unwanted increase in local tissue temperature. The application of a higher voltage allows regions of tissue further away

from the energy delivery device to reach a temperature at which a lesion can form, thus increasing the side/volume of the lesion.” (*Id.* at 3:65–4:7.)

43. Avanos Medical Sales, Inc. is the assignee of all rights, title, and interest in the ’755 patent, and has the right to bring this suit for injunctive relief and to recover damages for any current or past infringement of the ’755 patent.

### **COUNT**

#### **Infringement of The ’755 Patent**

44. The preceding paragraphs are incorporated by reference as if fully stated herein.

45. The ’755 patent is valid and enforceable.

46. Medtronic sells internally cooled probes as part of the “enhanced” Accurian system. These internally cooled probes are used to deliver RF energy to a patient’s body to ablate nervous tissue.

47. Medtronic, directly or through the actions of its employees, divisions, and/or subsidiaries, has infringed, and continues to infringe, one or more claims of the ’755 patent under 35 U.S.C. § 271(a), for example, but not limited to, claim 1, either literally and/or under the doctrine of equivalents, by making, using, selling, and/or offering for sale in the United States, and/or importing into the United States, products and/or methods encompassed by those claims, including for example, by making, using, selling, offering for sale, and/or importing the Accused Products.

48. Medtronic has no license for the ’755 patent.

49. Medtronic does not acquire the Accused Products from a licensee of the ’755 patent.

50. Third parties, including Medtronic's customers, have infringed, and continue to infringe, one or more claims of the '755 patent under 35 U.S.C. § 271(a), either literally and/or under the doctrine of equivalents, by using the Accused Products supplied by Medtronic.

51. Medtronic, directly or through the actions of its employees, divisions, and/or subsidiaries, has induced infringement, and continues to induce infringement, of one or more claims of the '755 patent under 35 U.S.C. § 271(b), for example, but not limited to, claim 19. Medtronic actively, knowingly, and intentionally induced, and continues to actively, knowingly, and intentionally induce, infringement of the '755 patent by selling or otherwise supplying Accused Products; with the knowledge and intent that third parties will use the Accused Products supplied by Medtronic to infringe the '755 patent; and with the knowledge and intent to encourage and facilitate the infringement through the dissemination of the Accused Products and/or the creation and dissemination of promotional and marketing materials, supporting materials, instructions, product manuals, and/or technical information related to the Accused Products.

52. Avanos has been and continues to be damaged by Medtronic's infringement of the '755 patent, and has and will suffer irreparable injury unless and until that infringement is enjoined by this Court.

53. In committing these acts of infringement, Medtronic committed egregious misconduct, including, for example, acting despite knowing that its actions constituted infringement of a valid patent, or recklessly disregarding the fact that its actions constituted an unjustifiably high risk of infringement of a valid and enforceable patent.

54. Medtronic's infringement of the '755 patent was, and continues to be, deliberate and willful, entitling Avanos to increased damages under 35 U.S.C. § 284.

55. Medtronic's conduct in infringing the '755 patent renders this case exceptional within the meaning of 35 U.S.C. § 285, entitling Avanos to attorney fees and costs incurred in prosecuting this action.

**Prayer For Relief**

WHEREFORE, Avanos prays for judgment as follows:

- A. That Medtronic has infringed the '755 patent;
- B. That Medtronic, its officers, agents, and employees, and those persons in active concert or participation with any of them, and their successors and assigns, be permanently enjoined from infringement and inducing infringement of the '755 patent, including but not limited to the making, using, selling, and/or offering for sale in the United States, and/or importing into the United States, any devices, products, software, or methods that infringe the '755 patent before its expiration date;
- C. That Avanos be awarded all damages adequate to compensate it for Medtronic's infringement of the '755 patent, such damages to be determined by a jury and, if necessary to adequately compensate Avanos for the infringement, an accounting, and that such damages be trebled or otherwise increased under 35 U.S.C. § 284 and awarded to Avanos with pre-judgment and post-judgment interest;
- D. That this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that Avanos be awarded the attorney fees, costs, and expenses incurred in connection with this action; and
- E. That Avanos be awarded such other and further relief as this Court deems just and proper.

**Demand For Jury Trial**

Plaintiff Avanos hereby demands a trial by jury on all issues so triable.

Dated: November 4, 2019

Respectfully submitted,

s/ Albert C. Harvey

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*\* Motions for Admission Pro Hac Vice Forthcoming*